DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2015

NELIS
% Mr. Peter Chung
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K141715
Trade/Device Name: Glove Port
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OTJ
Dated: February 10, 2015
Received: February 23, 2015

Dear Mr. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141715

Device Name
Glove Port

Indications for Use *(Describe)*
The Glove Port is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[as required by 807.92(c)]

1. Applicant

1) Company : NELIS
2) Address :1005, 201-Dong Bucheon Techno Park Ssangyong 3-cha Samjeong-dong Ojeong-gu, Bucheon-si Gyeongggi-do, 421-742 Korea
3) Tel : +82(32)624-1697,
4) Fax : +82(32)624-1699
5) Homepage : www.nelis.co.kr
6) Contact person : Peter Chung, 412-687-3976
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : Apr. 23, 2014

2. Device Information

1) Trade Name : GLOVE PORT
2) Common Name : Endoscopy Surgery Instrument
3) Classification Name : Laparoscope, general & plastic surgery
4) Product Code : OTJ
5) Regulation Number : 876.1500
6) Class of device : Class II
7) Panel : General & Plastic Surgery

3. The legally marketed predicate devices :

① K073719 ASC TriPort Laparoscopic Access Device,
② K093372 SILS™ Port
③ K112196 Octo™ Port

4. Device description :

The Glove Port is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery. This device is single use and sterilized.

5. Intended Use :

The Glove Port is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.

6. Technological Characteristics :

The GLOVE PORT is laparoscopic instrument port which retracts a small abdominal incision to allow multiple laparoscopic instruments to pass through to the abdomen .

7. Performance data:

Bench testing is performed to demonstrate the functionality and mechanical safety as following items

a. comparative leak rate test to evaluate the leak rate without instruments, with instruments, and after vigorous manipulation of instruments vs. predicate device(s)
b. insufflation flow rate
c. insertion-withdrawal forces of instruments
d. determination of minimum size of skin incision
e. evaluation of GLOVE PORT device fixation

8. Predicate device comparison table

Manufacturer	NELIS				Covidien	Advanced Surgical Concepts
510(k) No.	K141715				K073719	K093372
Indication for use	The Glove Port is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.				The ASC TriPort Laparoscopic Access Device is intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.	The SILS™ Port is indicated for multiple instrument or camera access to the abdominal cavity through a single incision for performing minimally invasive laparoscopic procedures.
Product name	Endoscopy Surgery Instrument				Surgical Trocar	Laparoscopic Accessory
Trade name	Glove Port Original	Glove Port H	Glove Port A	Glove Port AT	SILSTM Port	ASC TriPort Laparoscopic Access Device
Model	60ea	14ea	33ea	9ea	3 ea	4ea
Product configuration						
Material	Polyurethane	Polyurethane	Polyurethane	Polyurethane	Silicone	Silicone
Port No.	3~4 ea				3 ea	3~4 ea
Absolute size	10mm~25mm				25mm	10mm~25mm
Installation and abdominal wall inner fixation	Wound retractor ring being fixed inside the abdominal wall inside.				Non-fixed	Distal ring being fixed in the abdominal wall inside.
Sterilization method	EO Gas sterilization				Gamma sterilization (Cobalt-60)	Gamma sterilization (Cobalt-60)
Certification	CE0120, ISO 9001:2008, ISO 13485:2003, Registration of KFDA				Registered 510(k) by FDA.	Registered 510(k) by FDA.

9. Conclusion:

The Device is investigated for function and effectiveness to compare the operation of function between Glove Port and predicate devices. Comparison results demonstrate that the specifications and performance of the device are same as functional and effective as the legally marketed predicate device.

Therefore, it is concluded that Glove Port is substantially equivalent to the legally marketed predicate device.

The performance tests demonstrated that GLOVE PORT is as safe, as effective and performs in a substantially equivalent manner to the predicate device.